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NOS. 09 - 993, 09 - 1039, & 09 - 1501

IN THE

Supreme Court of the United States

PLIVA, INC., ET AL., *Petitioners*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS ELIZABETH LLC, *Petitioner*,

v.

GLADYS MENSING, *Respondent*.

ACTAVIS, INC., *Petitioner*,

v.

JULIE DEMAHY, *Respondent*.

On Writs of Certiorari to the United States Courts of Appeals for the Eighth Circuit and for the Fifth Circuit

RESPONDENTS' PETITION FOR REHEARING

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RESPONDENTS' PETITION FOR REHEARING

Respondents Gladys Mensing and Julie Demahy hereby respectfully petition the Court to rehear *Pliva, Inc., v. Mensing*, No. 09-993; *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039; and *Actavis, Inc. v. Demahy*, No. 09-1501. Respondents seek rehearing because the judgment of the Court rendered on June 23, 2011 does not follow from the rule announced by the Court in this case. The Court overlooks the fact that the Petitioner generic drug companies could have "independently" complied with both state and federal law simply by suspending sales of generic metoclopramide with warnings that they knew or should have known were inadequate.

DISCUSSION

In the Opinion of the Court, this Court announced a new test for implied conflict preemption based on impossibility: "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Pliva, Inc. v. Mensing*, No. 09-993; *Actavis Elizabeth, LLC v. Mensing*, No. 09-1039; *Actavis, Inc. v. Demahy*, No. 09-1501, 2011 WL 2472790 (U.S. June 23, 2011), at *10 (citation omitted). The Court reasoned that "State tort law . . . required the Manufacturers to use a different, stronger label than the label they actually used," but that "Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels." *Id.* at *8. Therefore, because the Manufacturers could not independently change their labels, the Court found Respondents' failure-to-warn claims preempted.

But the Court's logic is erroneous, because it begins with a false premise. Contrary to the Court's reasoning, neither Minnesota nor Louisiana law required the Manufacturers to change their labels. Instead, what state tort law required was that the manufacturers not sell a drug that lacked adequate warnings. Resp'ts' Br. 29. The Petitioners could have satisfied this state law duty in either of two ways. As the Court recognized, Petitioners could have satisfied that duty by strengthening their warning labels; but that course of action required FDA approval and therefore could not have been accomplished independently. Alternatively, however, Petitioners could have satisfied their duty under state tort law by suspending sales of the product with a label that they knew or should have known was inadequate. *See Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) ("The generic defendants were not compelled to market metoclopramide. If they realized their label was insufficient but did not believe they could even propose a label change, they could have simply stopped selling the product"). That course of action was always available to them and could have been accomplished independently, without any action by the FDA.[1] Thus, it was not impossible for the Petitioners to comply with both federal and state law: they "could independently do under federal law what state law requires of" them.

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[1] Suspension of sales by the manufacturers of generic metoclopramide would not have risked injury to users of their products who needed access to the drug, because the name-brand product, Reglan, remains on the market. And the manufacturer of Reglan could have added an adequate warning to its label through the CBE process. *See Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009); 21 C.F.R. § 314.70(c).

A decision by Petitioners to stop selling generic metoclopramide with inadequate safety warnings would not only have satisfied their duties under Minnesota and Louisiana tort law; it would also have complied with their duties under the Federal Food, Drug, and Cosmetic Act (FDCA). As Justice Thomas noted in his concurrence in *Wyeth v. Levine*, "the statutory provisions governing FDA drug labeling, and the regulations promulgated thereunder, do not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA." 129 S. Ct. at 1210 (Thomas, J., concurring). Federal law prohibits the sale of misbranded drugs, 21 U.S.C. § 331, and deems a drug to be misbranded if it lacks "adequate warnings." 21 U.S.C. § 352(f)(2). Thus, Respondents' state law failure-to-warn claims "parallel" the duties imposed on drug manufacturers under federal law. This Court has repeatedly held that such parallel claims escape preemption, even under statutory schemes with express preemption provisions. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447-48 (2005); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). Indeed, so far as Respondents are aware, the decision in this case represents the first and only time this Court has ever held a traditional state-law cause of action preempted where the duties imposed by that cause of action were parallel to requirements imposed by federal law.

The ruling of this Court rested on a false premise regarding the duties imposed by state law; the actual state law duties paralleled federal law and could have been satisfied by Petitioners independently, without any action by the FDA or any

other party. This Court should therefore rehear these cases in order to address this error in its reasoning.

CONCLUSION

For the foregoing reasons, Respondents Gladys Mensing and Julie Demahy urge this Court to grant this petition for rehearing.

July 18, 2011

Respectfully submitted,

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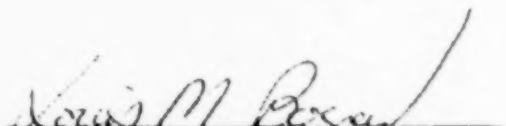
RESPONDENTS' RULE 44.1 CERTIFICATION OF COUNSEL

As counsel of record for Respondents Gladys Mensing and Julie Demahy, I hereby certify that this petition for rehearing is presented to the Court in good faith and not for purposes of delay.

July 18, 2011 Respectfully submitted,



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